DEC - 4 2000

ORASYSTEMS, LLC

555 PASSAIC AVE.
WEST CALDWELL, NJ 07006
PH 973-227-5505
FAX 973-227-1611
E-MAIL orasystems@earthlink.net

NOVEMBER 28, 2000

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION
DOCUMENT MAIL CENTER (HFZ-401)
9200 CORPORATE BLVD.
ROCKVILLE, MD. 20850

RE: K000846 TKD SCALERS

510(K) SUMMARY FOR TKD SCALERS

1. COMPANY NAME: ORASYSTEMS, LLC
555 PASSAIC AVE.
WEST CALDWELL, NJ 07006
2. DATE: NOVEMBER 28, 2000
3. CONTACT PERSON: BERNARD SESSMAN
ORASYSTEMS, LLC
PH 973-227-5505
FAX 973-227-1611
4. DEVICE NAMES: TKD SCALERS
AIRSON model - ROTARY SCALER
TITANUS model - ULTRASONIC SCALER
SELF TITANUS model - ULTRASONIC SCALER
5. PREDICATE INFORMATION:
THE LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS BEING CLAIMED ARE:
ROTARY SCALER - STAR DENTAL K782007
TACO DENTAL K831037
ULTRASONIC SCALER - PIEZON MASTER 400 K896749
PIEZO TRONIC K982793
SONIC SCALER K902413
6. INTENDED USE - THE TKD SCALERS ARE INTENDED FOR THE REMOVAL SUPRA AND SUBGINGIVAL CALCULUS AND STAINS FROM THE TEETH, SCALING AND ROOT PLANING.
7. DEVICE DESCRIPTION:
AIRSON model - PNEUMATIC SCALER WITH BODY IN LIGHT METAL ALLOY. THREE TIPS ARE INCLUDED WITH UNIT PLUS THREE OPTIONAL TIPS. THE UNIT'S FREQUENCY OF VIBRATIONS IS 5000 - 6200 HZ.
TITANUS model - ULTRASONIC PIEZO-ELECTRIC SCALER. THREE TIPS ARE INCLUDED PLUS THREE OPTIONAL TIPS. THE UNIT'S FREQUENCY IS 26,500 - 29,000 HZ.
SELF TITANUS model - COMPUTER CONTROLLED UNIT FOR USE WITH THE SELF TITANUS PIEZO-ELECTRIC UNIT. THREE TIPS ARE INCLUDED PLUS THREE OPTIONAL TIPS. THE UNIT'S FREQUENCY OF VIBRATIONS IS 26,500 - 29,000 HZ.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2000

Mr. Bernard Sessman
President
OraSystems, LLC
764 Speedwell Avenue, Suite 4
Morris Plains, New Jersey 07950-2231

Re: K000846
Trade Name: TKD Scales
Regulatory Class: II
Product Code: ELC
Dated: October 3, 2000
Received: October 11, 2000

Dear Mr. Sessman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K000846

DEVICE NAME: TKD Scalers

INDICATIONS FOR USE:

DENTAL SCALERS ~~SHOULD BE~~ USED BY TRAINED AND CERTIFIED DENTAL PROFESSIONALS, ONLY.
DENTAL SCALERS CAN BE USED FOR THE REMOVAL OF DENTAL PLAQUE AND TARTAR.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PA
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-U
(Optional Format

Susan Runner

(Division Sign-Off)
Control,

K000846